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**STATE OF DELAWARE**  
**BOARD OF PHARMACY**

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<b>PUBLIC MEETING NOTICE:</b>	<b>BOARD OF PHARMACY</b>
<b>DATE AND TIME:</b>	<b>Wednesday, January 17, 2018 9:30 am</b>
<b>PLACE:</b>	Conference Room A, 2 <sup>nd</sup> Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
<b>APPROVED:</b>	February 21, 2018

**MEMBERS PRESENT**

Hooshang Shanehsaz, R.Ph., Professional Member, President  
Bonnie Wallner, R.Ph., Professional Member  
Susan Esposito, R.Ph., Professional Member,  
Tejal Patel, PharmD, MBA, Professional Member, Vice President  
Kimberly Robbins, R.Ph., Professional Member  
Nicholas Juliano, PharmD, Professional Member  
Jay Galloway, Public Member

**MEMBERS ABSENT**

Gayle MacAfee, Public Member

**DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT**

Geoffrey N. Christ, R.Ph., J.D., Executive Secretary of the Board  
Eileen Kelly, Deputy Attorney General  
Christine Mast, Administrative Specialist III  
Michelle McCreary, Pharmacist Compliance Officer  
Jason Slavoski, Pharmacist Administrator (PMP)

**ALSO PRESENT**

Suzanne Raab-Ling  
Nick Petrovich  
Marlene Scadden  
Ryan Hines  
Debbie Hamilton  
Elizabeth Lewis  
Lisa C Flaherty  
Kevin Musto

**CALL TO ORDER**

Mr. Shanehsaz called the meeting to order at 9:32 a.m.

**REVIEW OF MINUTES**

A motion was made by Ms. Esposito and seconded by Ms. Wallner to approve the meeting minutes for October 18, 2017 with corrections. Ms. Patel abstained. The motion carried.

A motion was made by Ms. Robbins and seconded by Ms. Patel to table the November 15, 2017 meeting minutes. The motion unanimously carried.

### **UNFINISHED BUSINESS**

#### **Public Hearing @9:30 am – Proposed Rules and Regulations Changes –**

Ms. Kelly called the hearing to order and asked the Board to introduce themselves for the record. Ms. Kelly reviewed the proposed regulations changes. Public comment was received from Marlene Scadden, District Pharmacy Manager, Rite-Aid, regarding ICD 10 Codes or diagnosis on the prescription order. Ms. Scadden stated that there are no corresponding regulations or statute to support this change in the Board of Medical Licensure and Discipline. She also stated that a concern for increased communication between the Pharmacist and the Practitioner will cause undue burden on the Pharmacist and possible delay in therapy. Ms. Scadden stated that written comment will be submitted by February 1, 2018. Ms. Kelly stated that the public written comment period will remain open through February 1, 2018. Ms. Kelly asked that "Deliberations of Proposed Rules and Regulations changes be added to the February 21, 2018 agenda. The hearing concluded.

#### **Review and Signing of Final Orders**

None

#### **Statutory and Regulatory Discussion**

Review of 24 Del. C. Sec. 2533 (a) and Regulation 3.6 "Closing of Pharmacy When Pharmacist not Present" – Mr. Shanehsaz stated that changing the language to state premises instead of department would allow the Pharmacist the opportunity to leave the department for a break but stay on the premises. Mr. Christ and Ms. Kelly will provide additional information during the February meeting.

#### **Re-review of Tabled Application(s)**

PillPack Austin (TX), a motion was made by Mr. Galloway and seconded by Mr. Juliano to approve the application. The motion unanimously carried.

US Compounding Inc. (AR), a motion was made by Ms. Robbins and seconded by Mr. Galloway to approve the application. The motion unanimously carried.

### **PRESIDENT'S REPORT**

Mr. Shanehsaz received a letter from Accreditation Commission for Health Care (ACHC) a group that completes inspections focusing on Outsourcing. They would make themselves available to provide a presentation to the Board of their available services. Mr. Shanehsaz stated that this could be a means to have an inspection agency available to conduct inspections whenever the need would arise. Ms. Kelly asked if this would be a vendor, Mr. Shanehsaz stated they would. Ms. Kelly stated that current statute or regulation is not in place to support approving inspection vendors at this time. Ms. Kelly stated that business solicitation is not appropriate at this time. Ms. Kelly asked Mr. Shanehsaz to request more information in writing regarding their business model. Once regulation has been written a request for presentation could be requested at that time.

Mr. Shanehsaz stated that Chicago is currently working on Pharmacist workload restrictions to ensure patient safety. Chicago is proposing to limit Pharmacist workload to processing 10 patients per hour, adding required breaks.

Mr. Shanehsaz stated Delaware is working diligently on the Opioid epidemic.

### **NEW BUSINESS**

Mr. Shanehsaz read into the record the following ratifications:

#### **Pharmacist and Intern Licensure Approval Ratifications**

##### **Pharmacist:**

A1-0005156 Sumit H. Bhalodia  
A1-0005157 Kyle Zenon Rajkowski  
A1-0005158 Christina Ly  
A1-0005159 Erin Nicole Barton

A1-0005160 Laura Michelle Watkins  
A1-0005161 John K. Price  
A1-0005162 Nazaree Hines-Starr  
A1-0005163 Ashley E. Payne  
A1-0005164 Thomas Andrew Madej  
A1-0005165 Katherine Michelle Gibison  
A1-0005166 Rebecca Anne Straub  
A1-0005167 Aviva Y. Bodek  
A1-0005168 Kelly Ann Alexander  
A1-0005169 Edwin K. Langat  
A1-0005170 Heather Tyas  
A1-0005171 Thanh T Ngo  
A1-0005172 Darshna P. Patel  
A1-0005173 Jonette Lee Vagts  
A1-0005174 Capri J. DiGiovanni  
A1-0005175 Michael Torosian  
A1-0005176 Jennifer Amirhamzeh  
A1-0005177 Alicia R. Vickers  
A1-0005178 Ronald Joseph Zaycer  
A1-0005179 Sonia R. Darley  
A1-0005180 Jenny R. Liu  
A1-0005181 Mi Jang  
A1-0005182 Sandy Lim  
A1-0005183 Ryan A. Ung  
A1-0005184 Michael Lee Nguyen  
A1-0005185 Kevin Patrick Gallagher

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Pharmacist applications. The motion unanimously carried.

**Pharmacist Intern:**

A7-0002474 Samantha E. Cammisa  
A7-0002475 Jina H. Patel

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

**Non-Resident Pharmacy Licensure Approval Ratifications**

A9-0002090 Quaker Community Pharmacy, LLC  
A9-0002091 Orphan Pharmacy Services, LLC  
A9-0002092 McHugh Drug Store, LLC  
A9-0002093 Pet Rescue Rx, Inc.  
A9-0002094 Factor One Source Pharmacy LLC  
A9-0002095 Tailor Made Compounding  
A9-0002096 Biologics, Inc.  
A9-0002097 Costco Pharmacy #583  
A9-0002098 ABI Pharmacy  
A9-0002099 Cape Drugs  
A9-0002100 HomeCare Rx, Inc.  
A9-0002101 Castleton Pharmacy Corp.  
A9-0002102 Genesis Apothecary, Inc.  
A9-0002103 Confidential Drug, LLC  
A9-0002104 HHCS Pharmacy Inc.  
A9-0002105 MedMinder Systems, Inc.  
A9-0002106 Magellan Rx Pharmacy, LLC  
A9-0002107 Triad Isotopes  
A9-0002108 Over the Mountain Compounding Pharmacy

A9-0002109 Keystone Care Pharmacy  
A9-0002110 Successware, LLC dba The Pharmacie  
A9-0002111 PharmScript of MD, LLC  
A9-0002112 Caremark, L.L.C. dba CVS/Specialty #48604  
A9-0002113 PharmaPlus Pharmacy  
A9-0002114 1st Choice Pharmacy LLC  
A9-0002115 BSB Veterinary Corp dba Pet Value Mart  
A9-0002116 Level Care Pharmacy 1, LLC  
A9-0002117 Elwyn Specialty Care  
A9-0002118 WellDyneRx, LLC  
A9-0002119 Venice Pharmacy, LLC  
A9-0002120 Jubilant DraxImage Radiopharmacies, Inc. dba Triad Isotopes  
A9-0002121 Integrated HMO Pharmacy  
A9-0002122 Southside Pharmacy 3  
A9-0002123 Good Health Pharmacy  
A9-0002124 Pacific Pulmonary Services  
A9-0002125 MobiMeds dba The Pill Club

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

#### **Wholesale Distributor Licensure Approval Ratifications**

Ratification Listing – Wholesale Distributor

A4-0002456 Catalent CTS, LLC  
A4-0002457 AveXis, Inc.  
A4-0002458 SCA Pharmaceuticals, LLC  
A4-0002459 Catalent Pharma Solutions, LLC  
A4-0002460 WeCure Medicine LLC  
A4-0002461 RXQ Compounding, LLC  
A4-0002462 Ferndale Laboratories, Inc.  
A4-0002463 B. Braun Medical, Inc.  
A4-0002464 Sincerus Florida, LLC  
A4-0002465 The Rite Pharmacy, Inc.  
A4-0002466 Time-Cap Laboratories, Inc.  
A4-0002467 Hercules Pharmaceuticals, Inc.  
A4-0002468 Boston Medical Products, Inc.  
A4-0002469 AWC Specialty Rx Consulting, LLC dba Redmond & Greer Pharmacy Supply 2

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

#### **Medical Gas Distributor Licensure Approval Ratifications**

A2-0000150 Verus Healthcare, LLC

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Medical Gas Distributor applications. The motion unanimously carried.

#### **Manufacturer**

None

#### **Retail Pharmacy Licensure Approval Ratification**

A3-0001015 Aerenson Road Pharmacy, LLC

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

#### **Non-Retail Pharmacy Licensure Approval Ratification**

None

### **Outsourcing Facility**

AD-0000045 SCA Pharmaceuticals, LLC

AD-0000046 Central Admixture Pharmacy Services, Inc. (CAPS)

AD-0000047 RXQ Compounding, LLC

AD-0000048 Sincerus Florida, LLC

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

### **Request to Lift Suspension**

Jennifer Morris A1-0003750 – a motion was made by Ms. Esposito and seconded by Mr. Juliano to schedule a hearing to lift suspension. The motion carried.

### **Pharmacist Activation Request**

Sheri Richman - a motion was made by Ms. Robbins and seconded by Ms. Patel to approve the reactivation of the license. The motion carried.

Amir Yacoub - a motion was made by Ms. Wallner and seconded by Ms. Esposito to approve the reactivation of the license. The motion carried.

### **Board Review of Facility Applications**

Direct Success Pharmacy Dept. (NJ) - a motion was made by Mr. Galloway and seconded by Ms. Wallner to approve the application. The motion unanimously carried.

Pharmco, Inc. (CA) - a motion was made by Ms. Robbins and seconded by Mr. Galloway to approve the application. The motion unanimously carried.

JSPLTC, LLC. DbA: Curexa (NJ) - a motion was made by Ms. Robbins and seconded by Ms. Wallner to approve the application. The motion unanimously carried.

BDI, Pharma, LLC. (TX) - a motion was made by Ms. Esposito and seconded by Ms. Patel to table the application for the required floor plan. The motion unanimously carried.

BDI, Pharma, LLC. (SC) - a motion was made by Ms. Esposito and seconded by Ms. Patel to table the application for the required floor plan. The motion unanimously carried.

Royal Pharmacy (TX) - a motion was made by Ms. Wallner and seconded by MS. Esposito to approve the application. The motion unanimously carried.

Jubilant DraxImage Inc. (Canada) - a motion was made by Ms. Robbins and seconded by Ms. Esposito to propose to deny the application. The motion unanimously carried.

Glen Rock Medical Pharmacy (NJ) - a motion was made by Ms. Patel and seconded by Ms. Robbins to table the application. The motion unanimously carried.

Fountain Plaza Pharmacy (TN) - a motion was made by Ms. Robbins and seconded by Mr. Galloway to approve the application. The motion unanimously carried.

### **Board Review of Pharmacist Applications**

None

### **Review of Consent Agreement**

John Giacobello A1-0002847 - a motion was made by Ms. Esposito and seconded by Mr. Juliano to reject the consent agreement as presented. The motion unanimously carried.

Alton J. Chatmon A1-0003048 - a motion was made by Ms. Wallner and seconded by Ms. Esposito to approve the consent agreement as presented. The motion unanimously carried.

### **Continuing Education Review**

Jason Slavoski - Individual Program Approval - NASCSA Annual Conference, a motion was made by Ms. Wallner and seconded by Ms. Robbins to table the request for further review by the continuing education committee. The following information is requested: Certificate of completion (attendance), Proof that content meets the regulatory requirement, and the workshops attended. The motion unanimously carried.

David W Dryden - Individual Program Approval - NASCSA Annual Conference, a motion was made by Ms. Wallner and seconded by Ms. Robbins to table the request for further review by the continuing education committee. The following information is requested: Certificate of completion (attendance), Proof that content meets the regulatory requirement, and the workshops attended. The motion unanimously carried.

David W Dryden - Individual Program Approval - NABP District 4 Meeting, a motion was made by Ms. Wallner and seconded by Ms. Robbins to deny the request for continuing education. The motion unanimously carried.

### **Pharmacist and Pharmacy - Discussion/Action Items**

None

### **COMMITTEE REPORTS**

**Legislative** – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz, Bonnie Wallner and Gayle MacAfee

No Report

**Continuing Education** – Bonnie Wallner, Tejal Patel:

No Report

**Consumer Affairs** – Jay Galloway, Gayle MacAfee

No Report

**Professional Liaisons** – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

Ms. Robbins stated that DPS has changed their scheduled meetings on the Wednesday of the Board of Pharmacy meeting. There is a general membership meeting this evening.

**Controlled Substance Liaisons** – Tejal Patel, Hooshang Shanehsaz:

Ms. Patel stated that the committee reviewed the Board's request to remove the prescriptive requirement for syringes and agreed to begin the process to make those changes to the statutory requirements. This will be reviewed by the Secretary of State.

### **INSPECTION REPORT - Michelle McCreary**

Ms. McCreary reported the following inspection activities

- 3 – Substance Abuse Clinic Inspections
- 1 – Change of Ownership Pharmacy Inspections
- 1 – Research Facility Inspection
- 1 – Pre-Inspection Wholesale Distributor
- 1 – Wholesale Distributor Inspection
- 3 – Active Investigations

On November 29, 2017 Ms. McCreary and Ms. Kelly attended a meeting at NABP, regarding FDA Regulations, Pharmacist Compliance Officer, 797/800 compounding review.

Ms. McCreary stated there have been 3 armed robberies in the past 30 days. Ms. McCreary has observed that protocol is not followed, 106's are not completed and kept on file at the pharmacy, and notifying the DEA as well as notifying the Board is not being completed. Mr. Shanehsaz stated that the Pharmacist-In-Charge is responsible for all of these requirements. Mr. Christ will research further and contact the regional representatives of the chain pharmacies to provide guidance and feed-back. Ms. McCreary will begin to file complaints when she has observed blatant disregard of regulation.

Ms. McCreary stated that she has received the request from NABP regarding the “MPJE Item Writing” workshop being held March 4-6, 2018. Ms. McCreary suggested that Jason Slavoski should attend to assist with PMP questions on the exam. The Board agreed this should be considered. Mr. Christ will review and determine who will attend.

### **PMP REPORT – Jason Slavoski**

Mr. Slavoski reported the migration was completed on November 7, 2017. He provided some statistical information regarding users as follows:

7622 users approved with active account status (not necessarily logged in or users)

1264 are Pharmacist (there are 2317 Delaware licensed pharmacist in total)

4500 prescribers and 1200 pharmacist have not logged in or accessed the PMP since migration.

Mr. Slavoski provided a reminder to the Board that the sharing of PMP information with law enforcement, district managers and loss prevention is a felony and prohibited by law. This is in the acknowledgement agreed to for every report requested. Peer professionals can share information for the purpose of treatment only. Individual patients requesting their own PMP information must request it directly from the Division of Professional Regulations PMP Administrator. The request form is located on the PMP website. Pharmacies, Hospitals, and Practitioners are prohibited from providing this information to the patient. Law Enforcement may request this information from the Division of Professional Regulation; the request form is available on the PMP website.

Ms. Kelly is to provide the Board with information that can be noted on a prescription that has been refused by a pharmacy and returned to the patient.

Mr. Slavoski also provided 2017 statistics on the prescribing of controlled substances in Delaware: In 2017 there were 1.8 million prescriptions for controlled substances, 108 million tablets, which is a 46 million day supply this equates to 923 million morphine milli-equivalent's (MME). Mr. Shanehsaz stated that Delaware has a population of approximately 940,000. Mr. Slavoski continued his statistical report. Ranking by the number of prescriptions is as follows: the #1 drug prescribed was alprazolam, oxycodone was 2<sup>nd</sup> and generic Percocet was 3<sup>rd</sup>. The #1 by number of tablets dispensed was oxycodone with 14 million tablets. Ms. Esposito suggested that the Pharmacy Board's Medical Licensure and Discipline liaison share this information with that Board during their next meeting.

### **Pharmacist-In-Charge Interviews**

None

### **Physician Assisant Advisory Committee**

Mr. Shanehsaz had no report. The next meeting is scheduled for March 2018.

### **BOARD CORRESPONDENCE**

Mr. Shanehsaz reviewed the following correspondence with the Board.

Compounded and Repackaged Medications for Office-use Letter

Delaware State News - Delaware Joins in Settlement with Pharmaceutical Firm "Boehringer Ingelheim Pharmaceuticals, Inc.

NABP - Compliance Tools and Findings

NABP - Recommendation of the Task Force on the Regulation of Tele-pharmacy Practice

NABP - USP General Chapter <800> Implementation Delay until December 2019

### **OTHER BUSINESS BEFORE THE BOARD**

Mr. Shanehsaz stated that the Managed Care Organization (MCO) for medicaid is requiring the utilization of specialty pharmacies for HIV, HepC, and antipsychotic medications which is a concern due to decreased

access to medications. There are no specialty pharmacies located in Sussex County. Access to health care [medication] is an issue and a safety concern causing lapses in medication treatment. Abruptly stopping medications due to an inability to receive it could be life threatening. After reaching one of the MCO Directors after several weeks, Mr. Shanehsaz advised that statute and regulation allowed other pharmacies to fulfill this need so long as they accepted the conditions of payment. They seemed unaware of this provision and stated they would inquire with their national manager and have them contact Mr. Shanehsaz to discuss. He has not been contacted but will continue to reach out to them. Mr. Shanehsaz will also reach out to Secretary Walker, DHSS and Cynthia Denmark, Medicaid to express his concern.

Ms. Esposito stated that she would like to compose a letter of gratitude for Christine Mast and Team C to Mr. Mangler recognizing them for all of the outstanding support during the absence of an Executive Secretary of the Board of Pharmacy.

#### **PUBLIC COMMENT**

Mr. Musto stated he supports the any willing provider clause in legislation to assist with the specialty pharmacy issue with the MCO's for Medicaid. Mr. Musto also has concerns regarding interpreting notes written on prescription order by a pharmacist and if it is allowed. Notes written often are for prescriptions that are attempted to be filled earlier than permitted and noted by writing on the prescription order "too soon to fill". Ms. Kelly stated she would review the statute and regulations and report back to the Board.

Ms. Restano-Flaherty, DPS-Public-Professional Regulations stated that she has been a pharmacist since 1989. She will be more involved in creating relationships with the Board.

Mr. Ryan Hines President, DPS questioned the use of the PMP and disclosure to providers. Ms. Kelly stated that sharing of PMP information is prohibited and should not be shared with any prescriber that is not authorized to have access to the PMP. Mr. Slavoski stated that conferring with the prescribing practitioner regarding patient care is allowed. Ms. Kelly will provide the Board with more information at a later date.

#### **NEXT SCHEDULED MEETING**

The next meeting is scheduled for February 21, 2018 at 9:30 a.m., 2nd Floor Conference Room.

#### **ADJOURNMENT**

There being no other business before the Board, a motion to adjourn the meeting was made by Ms. Patel and seconded by Ms. Robbins at 1:01 pm. The motion unanimously carried.

Respectfully submitted,

A handwritten signature in black ink that reads "Mast". The signature is cursive and stylized, with the first letter being a large capital 'M'.

Christine Mast  
Administrative Specialist III  
Liaison, Board of Pharmacy